UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,715	08/14/2001	Moncef Jendoubi	266/226	1686

34313 7590 05/18/2007

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

MAIL DATE	DELIVERY MODE
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	09/930,715	JENDOUBI, MONCEF	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/2007 has been entered.

Status of Claims

Claims 14-21 are pending and under consideration in this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection).

Claim 14 drawn to "providing a plurality of antibodies each having a signaling element" is not supported in the as filed specification. The as-filed specification does not define or describe what constitutes a "plurality" of antibodies. Likewise, the broad claimed "signaling element" is not supported in the original specification which discloses specific signaling elements. MPEP 714.02 clearly states that when amendments to the claims are made, applicants are to specifically point out the support in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 14 is indefinite as to the human tissue samples "derived" from different biological conditions. It is unclear as to the manner the samples are **derived** or which portion of which different conditions the tissues are derived. The step of "containing" at least two samples appears grammatically incorrect. "Obtaining" seem more appropriate for the first step of the method. It is unclear whether the different biological conditions are expressed in a single tissue sample.

2. Claim 14, Step b "containing the proteins in discrete areas of an array that physically separate the at least two samples" is unclear. How is the proteins contained in the discrete areas of an array? "Contacting" appears more to be the appropriate step. How is the physical separation in the array

among the samples achieved by simply containing the protein in the array? It is not clear whether in the providing step, the antibodies identified that has specific binding affinity to an expression product of a gene sequence is the same or different from step(a) expressed gene products.

3. It is not clear as to the "specific" binding affinity to an antibody in terms of the kind of expressed products it is considered specific thereto to the exclusion of the other products, especially in the absence of any identifying features of any components of the method.

4. The step of "correlating differences in the antibody binding reaction in the at least two samples with expression of the gene sequence identified with the member of the plurality of antibodies" is confusing as to the identification step being achieved.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re*

Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/945,543('543 application) or claims 1-9 of copending application 10/945,784('784). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method is similar to the methods of either the '543 or '784 application except the instant method affixes the protein products in an array as opposed to the copending applications with the antibody affixed to the array. However, it would have been obvious to affixed either the protein products (i.e., antigen) or antibody on the array with a reasonable expectation of achieving the same results i.e., identifying of the protein (antigen) present in the diseased state.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Maintained Rejection(s) Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenchik et al. (US Patent 6,087,102).

Response to Arguments

Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Chenchik et al. (US Patent 6,087,102) for claims 14, and 17-20 were considered but they are not persuasive for reasons of record and reiterated below.

Chenchik et al. disclose arrays of polymeric targets associated with the surface of the support and the method of using the array in high throughput gene expression analysis (see e.g. Abstract; col. 2, lines 3-11, and 51-62; col. 11, lines 3-23). The polymeric targets are biopolymeric compounds that include naturally occurring polymeric compounds or mimetics or analogues of naturally occurring polymeric compounds. The biopolymeric compounds includes peptides, polypeptides and proteins wherein they derived from cells or tissue extracts, which are derived from normal, disease, or condition state such

as cancer or exposure to toxic agents (see e.g. col. 3, lines 13-20, and lines 51-64). The polymeric targets are pattern on the support in a variety of configurations wherein each polymeric target are at a discrete location (see e.g. col. 5, lines 35-47). The method of using the array in high throughput gene expression analysis comprises the step of preparing the probe, contacting the probe with the array under conditions sufficient for probe to bind with corresponding target, removal of unbound probe from the array, and detecting the bound probe (see e.g. col. 8, line 55 thru col. 10, line 45). The probes include peptidic probes such as polyclonal antibodies and a labeled with a detectable label (see e.g. col. 9, lines 18-65). The assay determines both the expression level and the size of the target bound by the probe (see e.g. col. 11, lines 3-23). Thus, the method of Chenchik et al. anticipates the presently claimed invention.

Applicant argues that the reference of Chenchik et al. does not anticipate the presently claimed invention because Chenchik et al. do not teach or suggest the method steps of a "providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence" and "identifying differential gene expression

between the at least two distinct biological conditions by correlating differences in the antibody binding reaction in the at least two samples with expression of the gene sequence identified with the member of the plurality of antibodies". Thus, the reference of Chenchik et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Chenchik et al. do anticipate the invention of the instant claims. It is the examiner position is that Chenchik et al. do disclosed the instant claimed 'providing' step of instant claim 14 (col. 9, lines 25-30 and 58-61) and the claimed 'identifying' step of instant claim 14 (col. 10, line 65 up to col. 11, line 23). That is Chenchik et al. do disclose that the binding reaction of a particular antibody is linked to a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(col. 9, lines 58-61; col. 11, lines 12-23).

Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandaru (US Patent 6,462,187 B1; filing date of 6/15/2000) for reasons repeated below.

Bandaru discloses a method of comparing the level of expressed polypeptide before and after treatment of the disorder (e.g. biological conditions) (see e.g. col. 4, lines 9-13). The disorder includes cancerous condition (see e.g. col. 10, lines 21-55). The method of detection comprised of detecting the binding interaction of the antibody specific to the expressed polypeptide (see e.g. col. 37, lines 36-47). The method comprise of a two dimensional array having a plurality of addresses each address of the plurality is positionally distinguishable from each other address of the plurality (see e.g. col. 4, lines 35-45; col. 51, lines 37-67). Each address of the plurality can have a unique capture probe such as polypeptide, e.g. an antibody specific for the polypeptide. The plurality of addresses includes at least 10, 100, 500, 1,000, 5,000, 10,000, 50,000 addresses (see e.g. col. 49, lines 14-16). The array can be use to assay gene expression in a tissue to ascertain tissue specificity of genes in the array (see e.g. col. 49, lines 62-64) or to monitor expression of one or more genes in an array with respect to time for ascertaining differential expression patterns of one or more genes in normal or abnormal cells (see e.g. col. 50, lines 32-45). Additionally, the method of Bandaru does disclose the step of containing human protein samples in an array (see e.g. col. 4, lines 9-13) and refer to the analysis of

gene expression information in a tissue sample is derived from the differential binding reactions at two discrete sites of the array (see e.g. col. 4, lines 35-40, and 43-45; col. 49, lines 62-64). The method of Bandaru also disclose detecting the signal generated from a labeled attached to the antibody that binds to the probe of the array (see e.g. col. 51, lines 8-67). Therefore the method of Bandaru anticipated the presently claimed method.

Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Bandaru (US Patent 6,462,187 B1; filing date of 6/15/2000) for claims 14-21 were considered but they are not persuasive for the following reasons.

Applicant alleges that the reference of Bandaru does not anticipate the presently claimed invention because Bandaru do not teach or suggest the method steps of a) "providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence" and the method step of claim 15 wherein the antibodies are raised by in vivo immunization of a gene sequence. Thus, the reference of Bandaru does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Bandaru do anticipate the invention of the instant

claims. It is the examiner position that Bandaru does disclose the instant claimed 'providing' step of instant claim 14 (col. 51, lines 8-67) and the method step of claim 15 (col. 26, line 1 thru col. 30, line 10). That is, Bandaru does disclose that the binding reaction of a particular antibody is linked to a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(col. 50, lines 1-7; col. 51, lines 32-36 and 60-63). Therefore, the teachings of Bandaru do anticipate the invention of the instant claims, and the rejection is hereby maintained.

Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; filing date 7/14/1999) for reasons restated below.

Wagner et al. disclosed a method of comparing the protein expression of two cells or a population of cells that have been exposed to different conditions (see e.g. col. 37, lines 19-67). The method comprises an array of protein-capture agents arranged in discrete, known regions of patches (see e.g. col. 9, lines 66-67 to col. 10, lines 1-12). The array can have any number of a plurality of different protein-capture agents (see e.g. col. 11, lines 1-11). For instance, an array comprise of about 10,000 patches would comprise of about 10,000 different protein-capture

agents (see e.g. col. 11, lines 28-33). Therefore, the number of different protein-capture agents on an array will vary depending on the application desired (see e.g. col. 11, lines 12-13). The protein-capture agent would include biomolecule such as protein or polynucleotide (see e.g. col. 4, lines 48-67) and would binds specifically to the antibody of interest (see e.g. col. 12, lines 48-52). Additionally, the method of Wagner et al. does perform the method step of containing two tissue samples onto an array to obtain gene expression analysis because Wagner et al. define an array as an arrangement of entities in a pattern on a substrate (see e.g. col. 6, lines 61-64) and the array have plurality of different protein-capture agents (see e.g. col. 11, lines 1-4) (i.e. pluralities of different protein-capture agents are arranged in a pattern on a substrate). Wagner et al. discloses that protein-capture agents are proteins in a cell that specifically binds to another protein such as an antibody (see e.g. col. 12, lines 50-52). The method of Wagner et al. also disclose detecting the signal generated from a labeled attached to the antibody that binds to the protein-capture agents of the array (see e.g. col. 34, lines 10-43). Therefore the method of Wagner et al. anticipates the presently claimed method.

Applicant's arguments directed to the rejection under 35 USC 102(b) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; filing date 7/14/1999) for claims 14-21 were considered but they are not persuasive for the following reasons.

Applicant contends that the reference of Wagner et al. does not anticipate the presently claimed invention because Wagner et al. do not teach or suggest the method steps of a) "providing a plurality of antibodies each having a signaling element when each member of the plurality of antibodies is identified as having specific binding affinity to an expression product of the gene sequence" and the method step of claim 15 wherein the antibodies are raised by in vivo immunization of a gene sequence. Thus, the reference of Wagner et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Wagner et al. do anticipate the invention of the instant claims. It is the examiner position is that Wagner et al. do disclosed the instant claimed 'providing' step of instant claim 14 (see e.g. col. 34, lines 10-43; col. 36, lines 51-65; col. 37, lines 54-67) and the method step of claim 15 (col. 26, line 37 thr col. 28, line 26). That is Wagner et al. do disclose that the binding reaction of a particular antibody is linked to

a particular gene for the label, which associated with the probe (antibody), provide a signal only when the probe is specifically bound to the target molecule (gene)(see e.g. col. 36, lines 51-65; col. 37, lines 1-36). Therefore, the teachings of Wagner et al. do anticipate the invention of the instant claims, and the rejection is hereby maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 5, 2007